

## Effectiveness of sodium picosulfate/magnesium citrate without diet vs. sennoside with diet in bowel preparation

Diet is not mandatory in bowel preparation

Ramazan Saygın Kerimoğlu<sup>1</sup>, Süleyman Kargın<sup>2</sup>, Alpaslan Şahin<sup>1</sup>

<sup>1</sup> Department of General Surgery, Konya City Hospital, Konya

<sup>2</sup> Department of General Surgery, Medical Faculty, Karatay University, Konya, Turkey

### Abstract

**Aim:** A three-day diet in bowel preparation before undergoing colonoscopy is an important factor that affects patient compliance. This study aimed to compare the effectiveness of sodium picosulfate/magnesium citrate without a diet and rectal enema application protocol and conventional sennoside protocol before colonoscopy.

**Material and Methods:** This is a prospective, single-centre, investigator-blinded, randomized study. A total of 60 patients were recruited: 30 in the sennoside group and 30 in the sodium picosulfate/magnesium citrate group. All procedures were performed by an experienced endoscopist who was blinded to the bowel preparation protocol. The Ottawa Bowel Preparation Scale was used by the endoscopist to assess the bowel preparation state.

**Results:** The effectiveness of bowel cleansing regimens was similar in the entire, right, transverse, descending, and rectosigmoid colon according to the Ottawa Bowel Preparation Scale ( $p>0.05$ ). There was no difference between the groups in terms of cecal intubation rates, the detection of polyps, and the number of polyps.

**Discussion:** The use of sodium picosulfate/magnesium citrate is an effective bowel cleansing agent and can provide both successful colonoscopy and patient compliance without a three-day fiber-free diet.

### Keywords

Bowel Preparation, Sodium Picosulfate/Magnesium Citrate, Diet-Free Colonoscopy, Sennoside

DOI: 10.4328/ACAM.20810 Received: 2021-08-07 Accepted: 2022-04-18 Published Online: 2022-04-27 Printed: 2022-06-01 Ann Clin Anal Med 2022;13(6):592-596

Corresponding Author: Süleyman Kargın, Department of General Surgery, Medicana Konya Medical Faculty, Karatay University, Feritpasa Street, Konya, Turkey.

E-mail: drs.kargin@hotmail.com P: +90 332 221 80 80

Corresponding Author ORCID ID: <https://orcid.org/0000-0003-4597-8654>

## Introduction

Colonoscopy is a widely used procedure for diagnosing and treating colon and terminal ileum pathologies. Adequate bowel cleansing is essential for the detailed visualization of the mucosa of the entire large intestine and the quality of the colonoscopy procedure [1].

An ideal bowel preparation method should be effective in cleansing the bowel and be well tolerated by the patients. Factors that adversely affect patient compliance are the need for a three-day diet and high fluid intake during the bowel cleansing process, unexpected symptoms such as abdominal pain, vomiting, cramps after drug intake, and enema applications. Polyethylene glycol (PEG), sodium phosphate, and sennoside group drugs are commonly used for bowel cleansing before colonoscopy. Although PEG is seen as the gold standard in bowel cleansing, some patients cannot tolerate it well due to its taste and need for high volume ingestion [2]. Sodium phosphate group agents are a better option in terms of patient compliance, but they bring concerns due to possible negative adverse effects [3,4]. In our country, sennoside and sodium phosphate groups are frequently used for colon preparation and these protocols require a three-day diet and enema application. The sodium picosulfate/magnesium citrate (SPMS) protocol is a well-tolerated intestinal cleansing agent due to low volume fluid requirement and good taste. The European Gastrointestinal Endoscopy Association [5] recommends SPMS as an alternative to PEG solutions because of its less frequent adverse effects and an equivalent colon cleansing rate. The effects of sodium picosulfate/magnesium citrate agents on bowel cleansing in both classic protocols and divided doses have been compared in many studies [6-8]. However, we found no study in the literature that evaluated the effects of SPMS agents on bowel cleansing without a fiber-free diet.

The aim of our study was to compare the effectiveness of the SPMS protocol, which is used without diet and enema, and the sennoside protocol, which requires a three-day diet and a rectal enema for bowel preparation before colonoscopy.

## Material and Methods

This was a prospective, single-center, investigator-blinded, randomized study evaluating the effect of two different bowel preparation protocols on adequate bowel preparation. Our study was conducted in accordance with the ethical standards of the World Medical Association Helsinki Declaration Principles. This study was approved by the KTO Karatay University Medical Faculty Ethics committee (approval number: 2021/035).

### Patients

The study included patients aged 18-80 years who presented to the general surgery outpatient clinic due to colorectal cancer screening or nonspecific gastrointestinal symptoms between January and April 2021. Exclusion criteria were pregnancy or breastfeeding, history of colon resection, intestinal obstruction, presence of serious comorbid diseases (e.g. heart, kidney and hepatic failure), presence of psychiatric disease, and unwillingness to participate in the study. Written informed consent was obtained from all patients who agreed to participate in the study. Before the colonoscopy procedure, patient information including age, sex, colonoscopy indications,

previous surgery, and colonoscopy procedures were collected.

### Randomization

The participants were enrolled by a clinical coordinator nurse. The coordinator nurse randomly assigned the patients into two bowel preparation protocol groups (1:1) according to the order of patient arrival. Numbered sealed envelopes were used to ensure confidentiality of distribution. The endoscopists and researchers were unaware of the distribution of the groups. The diet protocols and the bowel cleaning agents to be used were explained to each patient in detail by the coordinator nurse. The patients were advised not to ask any questions or give information to the endoscopists and the endoscopy staff about the bowel preparation protocol.

### Protocol

Patients in the first group (sennoside group) were given a list of foods they could and could not eat, and a clear diet was recommended for three days before the colonoscopy. Patients were told to drink a total of 500 ml sennoside solution (250 mL X-M Diet Solution Laxative® (containing 0.5 g Sennosid A + B calcium), Yenişehir, Turkey) 250+250 mL the day before the colonoscopy, at 14:00 and 18:00 PM. Patients were also warned to apply a total of two bottles of 210 mL rectal enema (B.T. enema® 210 mL, Mediterranean Lab Tic. Ve San CO., LTD, Ankara, Turkey) the night before the colonoscopy at 22:00 PM and in the morning of the procedure at 08:00 AM. Patients in the second group (SPMS group) were given two sachets of SPMS, each containing sodium picosulfate (10 g), magnesium oxide (3.5 g) and citric acid (12 g) (Picoprep®, Ferring Arzneimittel Ges.mbH, Vienna, Austria). They were told to prepare each sachet by mixing it with 150 mL of water and to drink it at 16:00 PM and 22:00 PM on the day before the colonoscopy procedure. Patients were also advised to consume at least five glasses of water after each solution. The patients in this group did not receive a rectal enema.

Patients in both groups were instructed to consume clear liquids such as water or tea, until the consistency and color of the stool became like water until 24:00 PM. Patients were advised to have a liquid diet breakfast on the morning of the colonoscopy. All colonoscopies were performed between 13:00 PM and 18:00 PM.

### Procedure

All colonoscopy procedures were performed under propofol-based sedation. A Fujinon System 4400XI© (Fujinon Inc, Tokyo, Japan) colonoscopy device was used in the procedures. During the colonoscopy, the patients' blood pressure, heart rate, and peripheral oxygen saturation were monitored, and their stability was ensured. All procedures were performed by an experienced endoscopist who was blinded to the bowel preparation method. The quality of bowel cleansing was scored by the endoscopist immediately after colonoscopy according to the Ottawa Bowel Preparation Scale (OBPS), which is scored from 0 to 4 (Table 1) [9]. The adequacy of colon cleansing was evaluated both as the entire colon and separately (ascending, transverse, descending, and rectosigmoid colon) according to the OBPS. In OBPS scores, 3 and 4 are accepted as insufficient bowel cleansing. In addition, the data of whether cecal intubation was performed, detection of polyps, and the number of detected polyps were added to the form. The data from the colonoscopies were

written on a form and put in a sealed envelope and handed over to the coordinator nurse.

**Statistical Analysis**

In statistical calculations, the mean, standard deviation, median, lowest, highest, and ratio values were used. The distribution of variables was measured using the Kolmogorov-Smirnov test. The Mann-Whitney U test was used to compare numerical variables between groups. The Chi-square or Fisher’s exact test was used to compare categorical variables. Statistical analyses were performed using the IBM SPSS Statistics for Windows, Version 21.0 software package (2012 Armonk, NY: IBM Corp). The level of statistical significance was accepted as  $p < 0.05$ .

**Results**

A total of 67 patients were included in the study. Seven patients (three in the sennoside group and four in the SPMS group) whose

**Table 1.** Bowel cleansing assessment scale (Ottawa Bowel Preparation Scale)

Assessment of right mid rectosigmoid colon	
0.	No liquid, mucosal detail clearly visible
1.	Minimal liquid, mucosal detail visible without the need for washing or suctioning
2.	Mucosal detail becomes visible with suctioning
3.	A reasonable view is obtained with suctioning and washing
4.	Solid stool obscuring mucosal detail and not cleared with washing and suctioning
Assessment of the entire colon	
1.	Small amount of fluid
2.	Moderate amount of fluid
3.	Large amount of fluid.

**Table 2.** Demographic data of patients according to bowel preparation protocols

	Sennoside		Sodium Picosulfate-Magnesium citrate		p
	Mean ± SD		Mean ± SD		
	n (%)		n (%)		
Age	51.06±12.85		47.50±16.37		0.344
Gender	Male	15 (50)	19 (63.3)		0.435
	Female	15 (50)	11 (36.7)		
Indication	Screening	9 (30)	12 (40)		0.264
	symptom	21 (70)	18 (60)		

M: mean SD: standard deviation n: number of patients

**Table 3.** Bowel cleansing data

Mucosal cleanliness adequacy	Sennoside	SPMC	p	
Adequate cleaning n (%)	adequate	23 (76.7)	23 (76.7)	0.748
	inadequate	7 (23.3)	7 (23.3)	
OBPS Scores				
Mean scores (SD)*				
Ascending colon	1.93 (1.04)	1.90 (1.21)	0.982	
Transverse colon	1.16 (1.34)	1.46 (1.35)	0.353	
Descending colon	0.70 (1.14)	1.16 (1.31)	0.142	
Rectosigmoid	0.33 (0.66)	1.16 (1.31)	0.208	
Entire colon	1.46 (1.07)	1.43 (1.27)	0.903	

\*Ottawa Bowel Preparation Scale, SPMC: Sodium Picosulfate-Magnesium citrate. SD: Standard Deviation

colonoscopies could not be completed were excluded from the study. Accordingly, 60 patients (30 in the sennoside group and 30 in the SPMS group) were included in the study. The mean age of the patients was  $49.31 \pm 17.70$  (range, 20-80) years, and 56.7% were male. There were no significant differences between the groups in terms of age, sex, and colonoscopy indication ( $p=0.344$ ,  $p=0.435$ , and  $p=0.264$ , respectively, Table 2). Most (65%) of the patients were referred to colonoscopy because of nonspecific gastrointestinal symptoms. In the SPMS group, more colonoscopies were performed for colorectal cancer screening (40% vs. 30%), whereas in the sennoside group, more colonoscopies were performed for gastrointestinal symptoms (70% vs. 60%).

All patients were able to tolerate both protocols. The most common problem in the sennoside group was enema intolerance, but this was not observed in the SPMS group because the patients did not receive a rectal enema. The most common adverse effect in both groups was abdominal pain. The number of patients with adverse effects was similar in both groups ( $p=0.532$ ).

The intestinal cleansing results are summarized in Table 3. Although the number of patients with adequate bowel cleansing in the entire colonoscopy evaluation was slightly higher in the sennoside group, there was no statistically significant difference between the groups (83.3% vs. 76.7%, respectively,  $p=0.748$ ). The mean OBPS scores were  $1.46 \pm 1.07$  in the sennoside group and  $1.43 \pm 1.27$  in the SPMS group and were similar between the two groups ( $p=0.903$ ). Regarding bowel preparation scores for the entire colon and each colon segment separately (ascending, transverse, descending, and rectosigmoid colon), there was no significant difference between the groups.

The cecal intubation rate was higher in the SPMS group than in the sennoside group, but the difference was not statistically significant [25(83.3%) vs. 21(70%),  $p=0.360$ ]. In addition, although fewer patients were detected to have polyps in the SPMS group, the average number of polyps detected was relatively higher than in the sennoside group. There was no significant difference between the groups in terms of the number of patients with polyps detected, and the average number of polyps ( $p=0.596$ ,  $p=0.454$ , respectively).

**Discussion**

In this prospective study, the efficacy of the classic sennoside protocol with a fiber-free diet for 3 days and SPMS solutions without diet on intestinal cleansing was evaluated. It was observed that the use of SPMS without dieting and the use of sennoside with a 3-day diet and rectal enema in preparation for colonoscopy yielded similar results. In addition, we found that rectal enemas caused discomfort to patients and more adverse effects were observed with the sennoside protocol.

Although the purpose of an ideal bowel cleansing method is to remove all fecal material sufficiently to clearly evaluate pathologic lesions, patient compliance with intestinal cleansing agents should not be ignored. Polyethylene glycol is accepted as the gold standard in bowel cleansing, but the need for a fiber-free diet and plenty of fluid consumption makes patient compliance difficult and unsuccessful bowel cleansing results can be seen [10]. Indeed, many studies have been conducted

comparing the effects of protocols involving PEG [10-12], Na-P [10,13], SMPS [11,14] and sennoside [12-14] agents. In most protocols, due to the negative aspects (3-day diet and bad taste of the agents), patient compliance problems are at high levels. This situation has led physicians to look for protocols that both provide effective bowel cleansing and increase patient compliance.

The pre-colonoscopy diet type is crucial for bowel cleansing, but surprisingly few studies have been conducted on this topic. Among the risk factors for inadequate bowel cleansing, dietary restriction is often seen as an integral component of bowel preparation, but can sometimes be overlooked. Current guidelines recommend the use of a low-fiber diet in addition to a full liquid diet the day before the colonoscopy [15].

Although most patients state that they understand their fiber diet and laxative practices, less than 20% follow a low fiber diet and approximately 75% follow a clear liquid diet only one day before the colonoscopy [16].

Therefore, it is becoming increasingly important to develop intestinal cleansing protocols that do not require a diet. The taste of the agents used and the adverse effects related to the drug also affect compliance [3]. For this reason, besides acceptable bowel cleansing, there is a need for a bowel preparation protocol that is easy to drink, requires less dieting, and has minimal drug-related adverse effects.

Sodium picosulfate/magnesium citrate solutions are becoming more popular in colonoscopy preparation. Similar or even better bowel cleansing results have been reported, especially when compared with PEG solutions. It has been reported in many studies that there is better patient compliance with this protocol due to its better taste and lack of need for large amounts of fluid intake [15,17-20]. We compared the use of diet-free SPMS with the sennoside protocol, which is widely used in our country. To our knowledge, the current study is the first randomized, prospective clinical study to investigate the effect of diet liberalization (diet free vs. clear liquid diet) during bowel preparation using SPMS in colonoscopy in healthy outpatients. Furthermore, our study had several distinct advantages over previous studies. Our study compared polyp detection and cecal intubation rates, which are accepted as important quality indicators for colonoscopy, as well as bowel cleansing quality between the two study groups. Similar results were obtained in a study comparing SPMS and sennoside agents; however, no dietary restriction was applied in the use of either agent [14]. In our study, no difference was found between the two protocols when we compared rates of both individual colon segments, entire colon cleansing assessments, and polyp detection rates (Table 3). Also, the rates of adverse effects were similar ( $p=0.532$ ). The most important limitation of our study was the small number of patients. We planned our study as a preliminary study because there was no previous experience with the dietless SPMS protocol. Satisfactory results will encourage this prospective study to be strengthened by larger series.

### Conclusion

According to the preliminary results of this study, the use of the SPMS protocol without dieting provides high patient compliance and sufficient bowel cleansing equivalent to the

sennoside protocol. If our results are confirmed in larger series, the use of SPMS without a diet protocol could be considered the preferred bowel cleansing protocol.

### Acknowledgment

Thank you to Akif ALTINBAS for his contributions.

### Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

### Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

### Funding: None

### Conflict of interest

None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

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**How to cite this article:**

Ramazan Saygın Kerimoğlu, Süleyman Kargın, Alpaslan Şahin. Effectiveness of sodium picosulfate/magnesium citrate without diet vs. sennoside with diet in bowel preparation. *Ann Clin Anal Med* 2022;13(6):592-596